



Innovative Medicines Initiative

# European Lead Factory Topic Workshop

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# Need for public-private collaboration



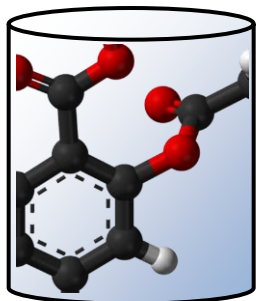
- ❑ Novel Lead Structures and Drug Targets are Innovation Drivers of the Early Small Molecule Drug Discovery Process
- ❑ Shift of Pharma discovery portfolio towards challenging (“intractable”) targets
- ❑ Limited access of academia to comprehensive compound collections and medicinal chemistry resources
- ❑ Combining strengths to enhance early drug discovery process for both, public and private projects

<i><b>Academia</b></i>	<i><b>Industry</b></i>
Knowledge Generation	Value Generation
Cutting-Edge Science	Risk-Balanced Portfolio
Multi-Disciplinary Networks	Operational Efficiency

# Objectives of the full project



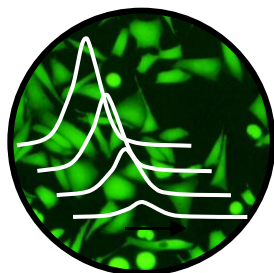
*Joint European  
Compound Collection*



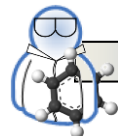
up to 500.000 cpds.

**X**

*Target/Assay*



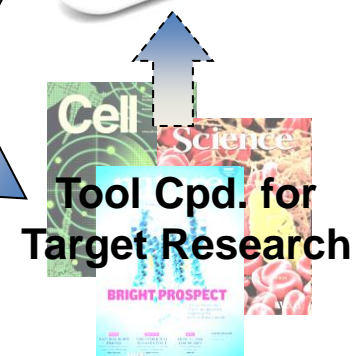
*Hit  
Characterization*



*MedChem  
Follow-Up*

*Qualified  
Hit List*

*Hit-to-Lead  
Optimization*

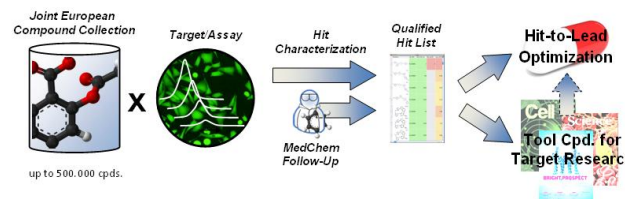


- ❑ Provide access to comprehensive, high-quality Joint EU Compound Collection
- ❑ Generate “Qualified Hits” for subsequent refinement in drug development process or serving as tool compounds in target research
- ❑ Establish novel platform to foster public-private collaboration
- ❑ Generate broad knowledge base (Qualified Hits x 240 projects) to directly exploit results or deduce future library design strategies

# Objectives of the full project



## The EU Lead Factory

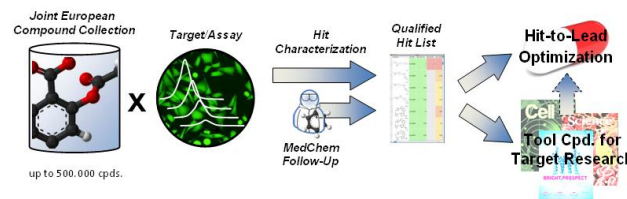


- Generate Comprehensive high-quality **Joint European Compound Collection**:
  - ◆ integrate industry's medicinal chemistry know-how
  - ◆ focus on value (IP) generation => unique, commercially non-available compounds
  - ◆ complement "Pharma Collection" by novel **Public Compound Collection**  
=> (i) differentiated chemistry, (ii) targeting 'intractable targets'
- Establish **European Screening Centre** as 'Centre of Excellence' for
  - ◆ housing and managing the Joint EU Compound Collection
  - ◆ development of target or pathway-specific bioassays
  - ◆ performing HTS for public projects
  - ◆ drive experimental hit characterization (selection) process
  - ◆ managing data flow and analysis ('honest broker concept') and project execution

# Objectives of the full project

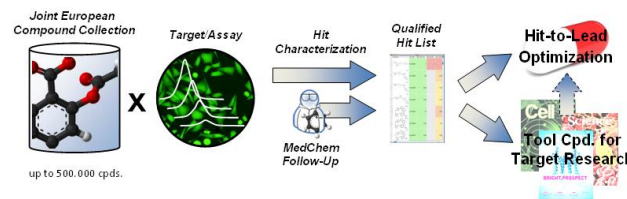


## The EU Lead Factory



- ❑ Project realization within time and budget frame requires operational efficiency
- ❑ Generation of “Qualified Hits”: medchem properties to match project purpose (Lead or Tool); qualification can include also limited chemistry follow-up activities
- ❑ Preference for public projects with relevance to research focus of EFPIA consortium (early partnering) → focus on innovation: No overlap with current or past pharma portfolio
- ❑ Information management to balance Intellectual Property (IP) generation with knowledge generation: Disclosure of structural information to project owner (and ultimately public) limited to Qualified Hit List

## The EU Lead Factory

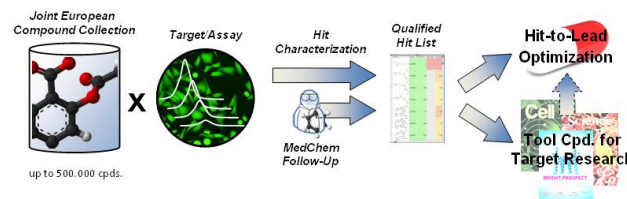


- Aims to provide industrial lead finding platform to academic programmes
  - (i) seeking quality tool compounds for target research  
=> validation of novel druggable targets
  - (ii) seeking quality compound candidates to enter drug optimization process  
=> exploiting also pharma collections outside industry focus for the benefit of patients
- Constitutes '*controlled experiment*' to broaden scope of pre-competitive research into early stage drug discovery : Collaborative exploitation of compound collections

# Expected impact on the R&D process



## The EU Lead Factory



- ❑ Ideally combines basic and applied research to translate cutting-edge research into early drug discovery programmes
- ❑ Provides platform to explore high-risk discovery approaches to share both, success stories and failures
- ❑ Provides novel aspect in pre-competitive research: Collaborative exploitation of compound collections in Screening Consortium

# Suggested architecture of the project



Applicant Consortium to establish

## Technology Platforms:

- ▶ *Screening Centre:* Leads or Tools
- ▶ *Library Synthesis:* Public Compound Collection

**EU Lead Factory** provides platforms to collect and translate academia's cutting-edge science to tangible 'qualified hits':

- ▶ *Screening Centre:* innovative discovery programs (→ target, pathway, assay) with a clear value proposition
- ▶ *Library Synthesis:* innovative library design proposals expanding chemical space through new synthetic methodologies or motifs addressing intractable targets



# Expected contributions of the applicants



Compound Logistics ■ Assay Development ■  
High-Throughput Screening ■ Hit Characterization ■  
Medicinal Chemistry Follow-Up ■ Data  
Management & Analysis ■ Project Management

▶ 48 HTS Projects *per anno*

full support for 24 public projects p.a.

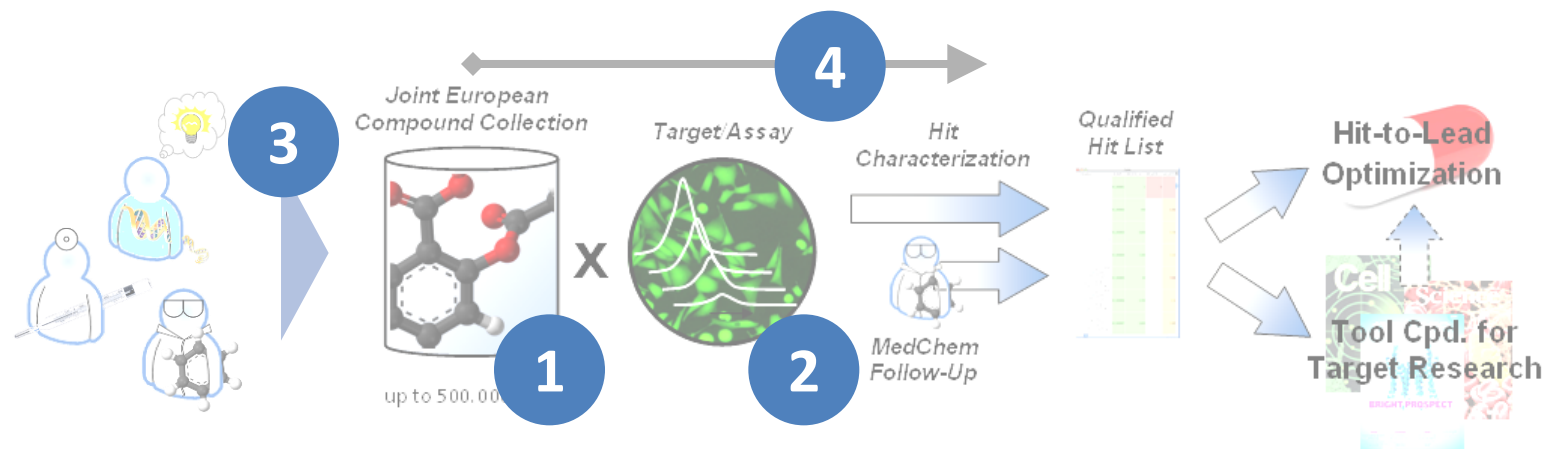
HTS for 24 private projects will be performed by EFPIA Participant

High-Throughput Chemistry ■ Compound Library  
Design ■ Chemoinformatics ■ Project Management

▶ up to 200.000 novel compounds  
(100.000 in the first 3 years)

▶ **Eols should address one of the 2 Sub-Topics; selected applicant groups eventually merge with EFPIA Consortium to generate Full Project Proposal**

# Expected (in kind) contributions of EFPIA members



1. High quality compounds from in-house collections (from automated and medchem synthesis): 50.000 cpds. → 4 HTS p.a.
2. Execution of private projects (from assay development to HTS) by EFPIA Participant → assay data, incl. test description, will be provided to Screening Centre
3. Expertise and know-how introduced in review & selection processes (Chemical Library and HTS Project Proposals)
4. Expertise and know-how supporting efficient project realization in Screening Centre; optional provision of assays for hit characterization

# What's in it for you?



## Academia

- ❑ Access to industry-like small molecule discovery platform to identify quality hit compounds translating cutting-edge projects to drug discovery or target research programmes
- ❑ Access to extended expert workbench to realize innovative chemistry proposals => introduce your chemistry to broad pharmaceutical screening activities
- ❑ Funding source to translate ideas into value

## SMEs

- ❑ Platform to establish early research collaborations
- ❑ Unique public-private consortium in the field of early drug discovery => focus on value (IP) generation

## Patients' Organizations

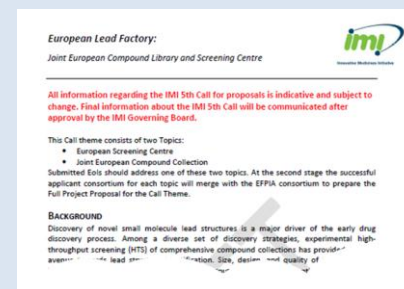
- ❑ Industry-like discovery engine for projects also outside of pharma focus (e.g. orphan diseases)

# Key deliverables of the full project



- ❑ Define processes, incl. internal and external interfaces, and division of work among participants
- ❑ Elaborate detailed governance structure
- ❑ Provide detailed planning for quantitative project goals, timelines and anticipated budget
- ❑ Formulate rules for information management, IP handling, and ownership as drafted in Topic Text

*within general framework described in the Topic Text:*



<http://www.imi.europa.eu>

- ❑ *Identify options to compensate for funding gaps*

# Questions?

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- Contact the **IMI Executive Office**

E-mail: [infodesk@imi.europa.eu](mailto:infodesk@imi.europa.eu)

Website: [www.imi.europa.eu](http://www.imi.europa.eu)